REMARKS

Favorable reconsideration is requested in view of the foregoing amendments and the following remarks.

I. Claim Status & Amendments

Claims 19-24 and 31-38 are pending in this application and stand rejected.

Claims 19, 31, and 38 are amended to further specify properties of the soluble branched polymers of glucose obtained by the process of the invention. Support can be found throughout the disclosure in general and in the soluble branched polymers of glucose obtained by the process in the working examples of the invention. No new matter has been added.

II. Enablement Rejection

Claims 19-24 were again rejected under 35 U.S.C. § 112, first paragraph, on the basis the specification fails to enable the full scope of the claims for the reasons set forth on pages 2-8 of the Office Action. The Examiner again argues that the specification enables a method involving certain specific branching enzymes, for example, *E. coli*, *C. reinhardtii*, or maize, but does not enable for such a method using any and all possible starch branching enzymes whatsoever expressed in any genetically modified expression.

Applicants respectfully traverse this rejection and submit that the specification does enable the full scope of the branching enzymes in the claimed method.

On page 3 of the Office Action, the Examiner states that "in order to use the claimed invention, one skilled in the art must possess the branching enzyme." It is believed that the specification clearly provides guidance and working examples demonstrating how to obtain and use the branching enzyme in the claimed method for the reasons discussed below.

Yet, it appears that the rejection (which is based on In re Wands) is written as though the present invention were directed to new branching enzymes with a new activity and to their process of preparation. However, it should be noted that this is not the case for the instant application.

Instead, the rejected claims of the invention are directed to a novel process for making soluble branched polymers of glucose containing essentially no beta-glucosidic bonds, from a starting product which is starch or a starch derivative and using the branching enzymes therein. The main chain is kept and additional chains are laterally branched onto this main chain. There is therefore an increase of size and weight of the molecule. The process, which is a combination of features, involves subjecting an aqueous solution of starch or a starch derivative (of 1 to 50% by weight dry matter) to a temperature greater than 130°C, and a pressure of more than 3.5 bars, for 2

to 5 minutes. The resulting starch or starch derivative is treated with 50 to 2,000 units of purified branching enzyme at a temperature between 25 and 50°C for 10 minutes to 24 hours, and the branched polymers of glucose thus obtained are collected. Starch is a polysaccharide carbohydrate forming a chain consisting of a large number of glucose monosaccharide units joined together by glycosidic bonds.

It should be noted that the claimed process provides technical means or a combination of technical means, which function to obtain a given result. The nature of the branching enzyme is but only one of several features recited in the combination of technical features in the claimed process. These features include: (i) starting product: an aqueous solution of starch or of starch derivative; (ii) aqueous solution of dry matter of 1 to 50% by weight; (iii) reaction temperature greater than 130°C; (iv) pressure of more than 3.5 bars; (vi) duration of 2 to 5 mins.; (vii) treatment of' the starch or starch derivative thus obtained with a purified branching enzyme; (viii) amount of branching enzyme 50 to 2,000 units; (ix) reaction temperature between 25 and 50°C; (x) duration from 10 mins. to 24 hrs.; (xi) collection of the branched polymers of glucose thus obtained. See, for instance, claim 19. It should be the branching enzyme is functionally defined in the claims. Accordingly, it should be clear that process of manufacturing the branching enzyme is not recited in the claims.

Nonetheless, the Official Action seemingly objects to the terms “purified branching enzyme” (claim 19) and the “branching enzyme is selected from the group consisting of glycogen branching enzymes, starch branching enzymes” (claim 22) on the basis that they are too broad as they encompass yet unavailable and undiscovered branching enzymes. In this regard, on page 3, the Examiner states, with respect to enablement and the claim breadth, that “the prior art does not reveal the isolation of each and every possible starch branching enzyme, or a representative sample thereof.” Applicants respectfully traverse this position.

Applicants need not disclose each and every possible starch branching enzyme in order to enable the claims. Indeed, this is quite normal practice in many technical fields where terms, such as “carriers”, “resilient means”, or “amplifying means” are common place and embrace new components, be they inventive or not. Not to mention, very often the generic indication of a kind of an article in the claim is followed by the non-exclusive term “comprising” and the characteristics of modifying features. This language leaves completely open the actual features of the rest of the article, apart from the necessity that its functioning should be as expected.

The above noted-examples show that the need for a fair protection governs both the considerations of the scope of the claims and of the requirements for sufficient disclosure. Unless variants of

components are also embraced in the claims, which are, now or later on, equally suitable to achieve the same effect in a manner which could not have been envisaged without the invention, the protection provided by the patent would he ineffectual.

The invention is sufficiently disclosed in the application as at least one aspect is clearly enabling the skilled person to carry out the claimed method. Consequently, any non—availability of some particular variants of a functionally defined component feature of the invention is immaterial to sufficiency as long as there are suitable variants known to the skilled person through the disclosure or common general knowledge, which provide the same effect for the invention. The disclosure need not include specific instructions as to how all possible component variants within the functional definition should he obtained. To require otherwise contravenes recognized US patent law.

Yet, on pages 4-5, the Examiner states that:

> in order to use any genetically modified organism capable of expression said enzyme, one skilled in the art would have to develop a wide variety of recombinant expression systems involving a large number of unrelated organisms and tissue cultures. This process would be highly unpredictable as many organisms are not well characterized and their suitability for protein expression is not known.

Applicants respectfully disagree and submit that the nature of the invention is not what the rejection asserts. As previously argued, it seems that the Examiner is imparting an unclaimed requirement on the invention, i.e., that of a new product directed to unknown branching enzymes. However, it is again noted that the claims are not directed to a process for the

preparation of new enzymes. Nor are the claims directed to new products.

Instead, the claims 19-24 relate to a novel process for making soluble branched polymers of glucose containing essentially no beta-glucosidic bonds. To implement the novel claimed process, one skilled in the art uses a branching enzyme. Applicants again respectfully submit that the term "branching enzyme" is a well recognized and conventional material/reagent used in the industry. An example of a conventional branching enzyme includes those of the EC 2.4.1.18 type.

Indeed, the Examiner seems to acknowledge this point at page 3 of Office Action, wherein it noted that branching enzymes are "known" and "common across a wide variety of species due to the ubiquity of starch as a storage medium".

In this regard, it is believed that such branching enzymes are readily obtainable as evidenced by the disclosure and the knowledge in the art. For example, in the last response, Applicants noted the following website, http://en.wikipedia.org/wiki/Glycogen branching_enzyme, which provides the following well-known definition of branching enzyme:

> "Every 10 to 14 glucose units a side branch with an additional chain of glucose units occurs. The side chain attaches at carbon atom 6 of a glucose unit, and the linkage is termed an alpha-1,6 glycosidic bond, To form this connection a separate enzyme known as a branching enzyme is used. A branching enzyme attaches a string of seven glucose units to the sixth carbon of a glucose unit, usually in an interior location of the glycogen molecule.

> This enzyme belongs to the family of transferases, specifically those glycosyltransferases that transfer hexoses (hexosyltransferases). The systematic name of this enzyme class is 1,4-alpha-D-glucan:1,4-alpha-D-glucan 6-alpha-D(1,4-alpha-D-glucano)-transferase. Other names in common use include branching enzyme,....."

In addition, the online-medical-dictionary (also discussed in the last response) defines the branching enzyme or 1,4-alpha-Glucan Branching Enzyme as follows:

> "In glycogen or amylopectin synthesis, the enzyme that catalyzes the transfer of a segment of a 1,4-alpha-glucan chain to a primaty hydroxy group in a similar glucan chain. EC 2.4.1.18."

Thus, as noted in the last response, the reference to EC 2.4.1.18 shows that the term branching enzyme is well known by its effect and is a generic term, irrespective of its source.

Again, what is important is the technical effect of the branching enzyme, *i.e.*, the side branching of additional chains of glucose units. Thus, Applicants submit that the process for preparing the branching enzyme and the original source of the branching enzyme have no major importance in the claimed method.

Also, as noted in the last response, the following websites are evidence that the branching enzyme is conventional, well known and readily obtainable in the art field: http://www.chem.qmul.ac.uk/iubmb/enzyme/EC2/4/1/18.html or http://www.expasy.org/enzyme/2.4.1.18, for examples of details of the EC2.4.1.18 enzyme (official IUBMB Enzyme Nomenclature). These clearly disclose that the branching enzyme in the claimed

process is well known and understood by those in the art field and the term is as being defined as:

Accepted name: 1,4-α-gluean branching enzyme.

Reaction: Transfers a segment of a (1→4)-alpha-D-glucan chain to a primary hydroxy group in a similar glucan chain.

Other name(s): branching enzyme; amylo-(1,4→1,6)-transglycosylase; Q-enzyme; alpha-glucan-branching glycosyltransferase; amylose isomerase; enzymatic branching factor; branching glycosyltransferase; enzyme Q; glucosan transglycosylase; glycogen branching enzyme; plant branching enzyme; alpha-1,4-glucan:α-1,4-glucan-6-glycosyltransferase; starch branching enzyme; 1,4-α-D-glucan:1,4-alpha-D-glucan 6-alpha-D-(1,4-alpha-D-glucano)-transferase.

Systematic name: (1→4)-alpha-D-glucan:(1→4)-alpha-D-glucan 6-alpha-D[(1→4)-α-D-glucano]-transferase.

Comments: Converts amylose into amylopectin. It is known that the accepted name can depend on the product, glycogen or amylopectin, *e.g.*, glycogen branching enzyme, amylopectin branching enzyme. The latter has frequently been termed Q-enzyme. Links to other databases include BRENDA, EXPASY, KEGG, ERGO, PDB, CAS, and have the following registry number: 9001-97-2.

Accordingly, the terms 1,4-α-glucan branching enzyme, branching enzyme, EC2.4.1.18 enzyme, etc. are considered to be equivalent and well known terms. As such, it is believed that term “branching enzyme” is a conventional and readily obtainable

material/reagent used in the process like HCl or water. It has official nomenclatures: such as official IUBMB Enzyme Nomenclature: EC2.4.1.18 enzyme. Thus, the process for preparing the branching enzyme and the original source of the branching enzyme are thus irrelevant in the instant case. Again, what is important is the technical effect of the branching enzyme, *i.e.*, the side branching of additional chains of glucose units (EC2.4.1.18. effect).

With respect to the Office's position on page 7 that the claims do not recite the term "conventional" in relation to "branching enzymes", Applicants submit that such is not necessary given that the recited term "branching enzymes" is itself conventional and well recognized generic language.

Contrary to the Office's position on page 6, Applicants' claims are a "hunting license" to obtain new and as yet discovered branching enzymes. The Applicants do not claim new products. Again, the present invention is not directed to discovering branching enzymes or new genes of such in new organisms. Thus, there is no need to try to discover and obtain new starch branching enzyme.

Instead, one skilled in the art, upon reading the disclosure and in view of the knowledge in the art, could readily obtain and use the conventional and well known branching enzyme as encompassed by the generic claim term "branching enzyme" in the claimed method without undue experimentation. To implement

the novel claimed process, one skilled in the art merely uses a conventional branching enzyme of the EC 2.4.1.18 type. Such branching enzymes are conventional and readily obtainable in the art field, and moreover, any one of which could be readily obtained and used in the claimed method without undue experimentation.

Further, beginning at page 15, the specification provides in detail guidance as to techniques and procedures for obtaining the branching enzymes for use in the claimed process. For instance, at page 15, lines 13-20, the specification notes that the purified branching enzyme can be one selected from the group consisting of the branching enzyme of *E. coli*, the branching enzyme of *C. reinhardtt* and the branching enzyme of maize. Nonetheless, it is again noted that any branching enzyme EC2.4.1.18 may be used.

Also, as to the Office's position with respect to the presence or absence of working examples, the Office contends that the working examples provided use of <u>one</u> specific enzyme, obtained from *Chlamidomonas reinhardtii*. This is not correct. The working examples (starting on page 17) exemplify the use of branching enzymes of very different sources. For instance, the specification demonstrates the use of branching enzymes, such as the glycogen branching enzyme of *E. coli* (a bacterial enzyme) and a branching enzyme of the green alga *Chlamydomonas reinhardtii* (a plant enzyme). Also, the specification generally discusses use of

branching enzymes, such as those from glycogen branching enzymes (such as the glycogen branching enzyme of *E. coli* (a bacterial enzyme), the starch branching enzymes, such as type I and type II starch branching enzymes of maize or unicellular algal starch, such as that from green algae *Chlamydomonas reinhardtii*. See page 15, lines 13-20. The specification even mentions use of branching enzymes from unicellular algae such as those prepared in the process described in French patent application no. 98/12051. See the discussion page 15, line 13 to page 17 ad Examples 1-4 on pages 17-24, with respect to sources, techniques for preparing the branching enzyme, and working examples.

It is believed that the skilled artisan could extrapolate from this guidance and the working examples how to obtain and use branching enzymes, such as those of the EC2.4.1.18 type in the claimed process without undue experimentation. The examples in the disclosure should be sufficient since the branching enzymes have the same effect of transferring a segment of a (1→4)-alpha-D-glucan chain to a primary hydroxy group in a similar glucan chain.

As to the quantity of experimentation necessary, it is again noted that what is important is the technical effect of the branching enzyme, *i.e.*, the side branching of additional chains of glucose units (EC 2.4.1.18.effect). Any EC 2.4.1.18 enzyme maybe readily obtained and used in the claimed process. In fact, hundreds of references to EC2.4.1.18 enzymes can be found in the

literature or on internet. Thus, the skilled artisan, upon reading the disclosure and in view of the knowledge in the art, could readily obtain any of the conventional branching enzymes of the EC2.4.1.18 type encompassed by the claims and then use them in the claimed process. This could be done using the routine techniques and procedures disclosed in the specification without undue experimentation.

Lastly, as further support of Applicants' position, it is again noted that the claims of OKADA (US 4,454,161) (cited in the prior art rejection) are not limited to the use of a specific branching enzymes. See for instance, claim 1 which recites "subjecting the aqueous solution to the action of a branching enzyme (EC 2.4.1.18) for a period sufficient to form substantial branches in the amylaceous substance. . ." This further supports the position that the terms branching enzyme and/or branching enzyme (EC 2.4.1.18) are equivalent and well recognized in the art field. Since 1,4-α-glucan branching enzyme, branching enzyme, EC2.4.1.18 enzyme, etc. are considered to be equivalent terms for the reasons discussed above.

Applicants would consider amending the claims to reflect this nomenclature along the lines of a branching enzyme (EC2.4.1.18) or purified EC2.4.1.18 enzymes, if the Office deemed that such an amendment would address this rejection. Such was suggested in the last response, but the Office did not address

this proposal. In the interest of compact prosecution, please comment on this proposal.

For these reasons, it is believed that the specification provides enabling support for the full scope of the branching enzymes of the claimed method. Thus, the above enablement rejection is untenable and should be withdrawn.

III. Prior Art Rejections

A. OKADA in view of SENKELESKI

Claims 19-22 and 38 were rejected under 35 U.S.C. § 103(a) as obvious over OKADA et al. (US 4,454,161) in view of SENKELESKI et al. (US 5,562,937) for the reasons on page 8-11 of the Office Action. This rejection is respectfully traversed for the reasons set forth in the last response filed June 30, 2008 and for the following reasons.

OKADA fails to disclose a method in which the starch is gelatinized by a treatment at over 130°C and 3.5 bars as recited in the instant claims. OKADA also does not disclose a method in which the amount of branching enzyme is between 50-2000 units and the reaction is carried out at exactly 30°C as recited in the claims. Thus, OKADA cannot render obvious treating a starch or starch derivative under the conditions recited in steps a) or b) of independent claim 19.

As noted in the last response, step a) of claim 19 requires that the recited starch or starch derivatives are

subjected to a relatively high temperature and pressure for a relatively short duration. This is different from the conventional gelatinization conditions utilized by OKADA. Conventional gelatinization conditions use milder conditions than those recited in step a) of claim 19. For example, to gelatinize waxy maize starch, the temperature is generally kept below 92° Celsius, the pressure is typically atmospheric, and the temperature is slowly raised to progressively reach the gelatinization temperature of the starch.

Also, Example B-4 of OKADA utilizes a heating step of between 140°C to 145°C. However, the amylaceous substance (i.e., wheat flour) is heated in the presence of the branching enzyme to effect the gelatinization and enzymatic reactions simultaneously. As such, Example B-4 of OKADA enzymatically treats the amylaceous substance at a temperature almost three times greater than that recited in step (b) (i.e., between 25 and 50°C) of claim 19.

Indeed, on page 9 of the Action, the Office acknowledges that OKADA fails to disclose a method in which the starch is gelatinized by a treatment over 130°C and at a pressure of 3.5 bars are recited in step (a) of claim 19. The Office also acknowledges that OKADA fails to disclose or suggest the amount of branching enzyme (between 50-2000 units) and the reaction temperature of 30°C as in step (b) of claim 19.

For these reasons, OKADA fails to disclose or suggest each and every element of the claimed method.

SENKELESKI is relied on for allegedly disclosing the temperature and pressure parameters and the amount of branching enzyme. However, it is believed that SENKELESKI fails to remedy the above-noted deficiencies of OKADA.

SENKELESKI relates to a method for digesting waxy starch with beta-amylase (column 1, lines 40-58). In order to be processed in this manner, SENKELESKI discloses that the starch is first steam cooked at a temperature of 120°C to 170°C at a pressure of about 4.1-5.5 bar.

Additionally, SENKELESKI discloses a method wherein the Office states that "[the gelatinized starch is enzymatically hydrolyzed] with beta-amylase or glucoamylase until up to about 60% by weight of the starch has been degraded to maltose or glucose" (Summary and claims 1 and 7)." Further with respect to SENKELESKI discloses a method wherein the Office states:

> "The enzyme reaction is continued until at least 5% and up to about 60% (preferably 15 to 35%,), by weight, of the starch has been degraded to maltose or glucose...
>
> "this exo-enzyme is capable of splitting the 1,4 linkages of the starch molecule but is not capable of splitting the 1,6 linkages, the residue of such degradation procedure is a compact molecular structure which is substantially free of outer branches or contains shortened outer branches. Alternatively, glucoamylase, an exo-enzyme which attacks the 1,4 linkages but also has limited activity with respect to the 1,6 linkages and results in the production of glucose and fragmented starch units may also be used.".

Further, it is well established that starch $(C_6H_{10}O_5)_n$ is a polysaccharide carbohydrate consisting of a large number of glucose monosaccharide units joined together by 1,4 linkages named glycosidic bonds. Glucose and maltose are well-known saccharides. Gluocse is a monosaccharide. Maltose is a disaccharide formed from two units of glucose joined with 1,4 linkage. The addition of another glucose unit yields maltotriose. Further additions will produce dextrins (also called maltodextrins) and eventually starch.

Based on the above knowledge, it is thus clear that in SENKELESKI, the main chain is cut into short pieces: monosaccharides or disaccharides. Therefore, there is an important decrease of size and weight of the treated molecule. According to the Examiner, a product obtained according to the method of SENKELESKI, made of monosaccharides (glucose) or dissacharides (maltose) would be used as the starting product in the process of OKADA.

However, this stands in contrast to the claimed method. As explained above, the present invention is directed to a novel process for making soluble branched polymers of glucose containing essentially no beta-glucosidic bonds by using a branching enzyme. See again the above definition for branching enzyme. Based on this definition and the instant disclosure, it is clear that in the method the present invention, not only the main chain is kept but also additional chains are laterally

branched onto this main chain. Consequently, there is an increase of size and weight of the molecule in the claimed process. This is exactly the opposite of what occurs in the process of SENKELESKI. In fact, SENKELESKI could be said to teach away from the process of the amended claims, which recite "the branched polymers of glucose thus obtained are collected, wherein the branched polymers of glucose comprise, at every 10 to 14 glucose units, an additional chain of glucose units." Indeed, the skilled artisan could not obtain the end products of the claimed method, where the branched polymers of glucose comprise, at every 10 to 14 glucose units, an additional chain of glucose units, if the starting product of SENKELESKI treated by the branching enzyme is only one or two glucose units. Such would make not sense. In this regard, it is believed that the combination of OKADA and SENKELESKI would not result in the claimed process. Consequently, the combination of OKADA and SENKELESKI is not predictive of the claimed process. In reply to the Office's position on page 10, the above discussion with respect to teaching away is the importance of the gelatinization step in SENKELESKI. In others, when combined with OKADA it would not arrive at the claimed method.

Further, it is well-settled that to support a rejection based on a combination of references, there must exist some motivation/rationale to make a change in the prior art teachings to establish *prima facia* case of obviousness.

Yet, the cited references provide no apparent reason for one skilled in the art to modify and/or combine the teachings of OKADA and SENKELESKI to arrive at the claimed method. Moreover, one of ordinary skill in the art would certainly not have been motivated to use the pretreatment-gelatinization step of SENKELESKI, because this gelatinization is shown to be useful for gelatinizing starch with the view of splitting a macromolecule into small or very small pieces, which stands in contrast to the present invention. Again, this contrasts the claimed method in which there is an increase of size and weight of the treated molecule, by branching lateral chains onto the said treated molecule.

For the above reasons, it is believed that the combination of SENKELESKI and OKADA would lead away from the amended claims. This is further evidence that the combination of SENKELESKI and OKADA is not predictive of the claimed method.

For these reasons, it is believed that SENKELESKI fails to remedy the deficiencies of OKADA.

Independent claim 19 is believed to be novel and nonobvious over the combination of SENKELESKI and OKADA. Claims 20-22 depend, either directly or indirectly on claim 19. Independent claim 38 corresponds to claim 19 but further defines the branching enzyme. Thus, these claims are also novel and nonobvious over the combination of SENKELESKI and OKADA for the same reasons with respect to claim 19.

Thus, the above-noted 103(a) obviousness rejection over OKADA and SENKELESKI is untenable and should be withdrawn.

B. Rejection over OKADA, SENKELESKI and SANDSTROM

Claims 31-37 were again rejected under 35 U.S.C. § 103(a) as allegedly obvious over OKADA in view of SENKELESKI and SANDSTROM et al. (PCT WO95/22562) for the reasons on pages 11-14.

This rejection is respectfully traversed for the same reasons set forth above with respect to OKADA and SENKELESKI and for the following reasons.

As discussed above, the Office's argument based on the combination of the teachings of OKADA and SENKELESKI is moot.

Furthermore, it is believed that the rejection employs improper a posteriori reasoning.

Also, it is worth recalling that the present invention is directed to a novel process for making soluble branched polymers of glucose and to the resultant soluble branched polymers of glucose themselves (claims 31-37), wherein the resultant soluble branched polymers of glucose contain essentially no β-glucosidic bonds.

By contrast, SENKELESKI discloses a method wherein the Office states that "[the gelatinized starch is enzymatically hydrolyzed] with beta-amylase or glucoamylase until up to about 60% by weight of the starch has been degraded to maltose or glucose" (Summary and claims 1 and 7)." Starting from this mono-

and disaccharide product, even assuming a branching enzyme would provide a reaction (according to its name, a branching enzyme is able to provide branches on a big/long molecule), what would be the reaction product of glucose or maltose? The answer is nothing, because there would be nothing long enough to be branched.

The starches of SANDSTROM differ from the claimed invention in that they do possess β-glycosidic linkages. Accordingly, SANDSTROM fails to remedy to the deficiencies of the primary and secondary references of OKADA and SENKELESKI.

For these reasons, independent claim 31 is believed to be novel and nonobvious over the combination of OKADA, SENKELESKI and SANDSTROM. Claims 32-37 depend, either directly or indirectly on claim 31. These dependent claims are believed to be novel and nonobvious over the combined cited references for the same reasons in view of their dependency on claim 31.

Thus, the above-noted 103(a) obviousness rejection over OKADA, SENKELESKI and SANDSTROM is untenable and should be withdrawn.

IV. Double Patenting Rejection

Claims 19-22 were again rejected on the ground of non-statutory obviousness-type double patenting over claims 1-4 of US 7,015,318 for the reasons on pages 141-5of the Office Action.

For the sole purpose of expediting prosecution and not to acquiesce to this rejection, Applicants attach herewith a terminal disclaimer for of US patent 7,015,318 to FUERTES et al. The terminal disclaimer overcomes the double patenting rejection. Withdrawal of the rejection is solicited.

V. Conclusion

There being no further outstanding matters, allowance of all the claims is solicited. Should there be any matters that need to be resolved in the present application; the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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APPENDIX:

The Appendix includes the following item(s):

- Terminal disclaimer